Please read this package insert carefully before use.

A Reagent for Detecting
Influenza A, B Viral Antigen
ImunoAce Flu

Important basic information

1. Diagnosis of influenza viral infection should be made based on an overall determination including not only the test result provided by this product, but also the results of other tests and the clinical symptoms.
2. If a pharyngeal swab is used as a specimen, pay special attention to the method of collection, as the test tends to be less sensitive than those of nasal swabs and aspirates.

General precautions:
1. The test plate should be used immediately after opening the packaging.
2. When it absorbs moisture, the quality deteriorates and an accurate result cannot be obtained.
3. Usage, dosage and instructions should be followed when using the kit.
4. This reagent can be used for in vitro diagnosis (IVD) in the countries where IVD approval is obtained. Any uses for the purposes other than IVD are not permitted.
5. Please use this reagent following the operational method described in this package insert. We are not liable to guarantee results obtained from any other operations and for any other purposes that are not described in the package insert.
6. In the specimen extracts contains sodium azide. If the solution enters the eye or mouth or adheres to the skin by mistake, take emergency measures such as thorough washing with water and receive medical treatment, if necessary.

Substances (kit components)

Test plate
- Components
  - Colloidal platinum-gold labeled anti-Influenza A, B virus monoclonal antibody (mouse)
  - Anti-Influenza A virus monoclonal antibody (mouse)
  - Anti-Influenza B virus monoclonal antibody (mouse)

Specimen extracts
- Components
  - Buffer, detergent, sodium azide

Indication, Effect (Intended use)
To detect Influenza A viral antigens and Influenza B viral antigens in nasal aspirate, nasal swab or pharyngeal swab (assistance for diagnosis of influenza virus infectious disease)

Test procedure (principles of the procedure)

This product is a test plate that consists of a carrier strip composed of a sample placing area, a reagent area that includes colloidal platinum-gold labeled anti-Influenza A and B virus monoclonal antibody (mouse) (hereinafter referred to as “colloidal platinum-gold labeled antibody A and B”) and a developing area that fixes the anti-Influenza A and B virus monoclonal antibody (mouse) (hereinafter referred to as “anti-Influenza A and B antibody”)
When a sample is placed on the sample placing area of the test plate, the colloidal platinum-gold labeled antibody A and B dissolves and forms an immune complex with the Influenza A and B viral antigens in the sample. This immune complex migrates through the developing area by capillary action, becoming captured by the anti-Influenza A or B antibody fixed in the developing area, and forms a black line of colloidal platinum-gold in the reading area [A] and/or [B]. This kit visually indicates the black line that shows influenza viral antigens exist in the sample.

Regardless of the existence of influenza viral antigens in the sample, excess colloidal platinum-gold labeled antibodies further migrate through the developing area, becoming captured by anti-mouse immunoglobulin antibodies fixed in the developing area, and form a black line in the reading area [C]. This means the colloidal platinum-gold labeled antibody have migrated normally.

Detection of influenza virus antigen by the immunochromatography

Precautions concerning operation
1. Collected specimens should be processed as soon as possible, according to the following preparation procedure.
2. All the specimens should be handled with extreme care, with all of them considered as posing a risk of infection.
3. Interfering substances

Blood and the following OTC drugs or prescription drugs had no effect on the judgment.

Whole blood (0.25%), one type of commercially available cold remedy (7.5 mg/mL), one type of commercially available cough drop (40 mg/mL), 2 types of commercially available eye drops (0.25 mL/mL), 2 types of commercially available nasal drops (0.25 mL/mL), 2 types of commercially available gargles (0.25 mL/mL), commercially available oral washing solution (0.25 mL/mL), acetylsalicylic acid (20 mg/mL), ambroxol hydrochloride (375 ng/mL), dequalinium hydrochloride (6.25 ng/mL), oxymetazoline hydrochloride (100 ng/mL), dried Platycodon extract (555 ng/mL), disodium cromoglycate (5 mg/mL), zanamivir (500 ng/mL), diphenhydramine hydrobromide (10 mg/mL), Naphazoline nitrate (125 ng/mL), (R)-(−)-phenylephrine hydrochloride (1 mg/mL), fluticasone propionate (127.5 ng/mL), chlorpheniramine maleate (5 mg/mL)

Usage, dosage (Procedures)
1. Methods of specimen collection

1) Sampling of nasal aspirate
   Firmly insert one tube of a sucking trap into the suction pump, and the other tube into a nasal cavity through an external nostril. Collect the nasal discharge aspirate in the sucking trap by operating the suction pump.
   Soak the attached swab in the relatively low viscous portion of the nasal aspirate collected avoiding the highly viscous portion or a solid portion.

2) Sampling of nasal swab
   Firmly insert the attached swab into the nasal cavity and collect mucosal cuticle by swabbing the nasal turbinates several times.

3) Sampling of pharyngeal swab
   Firmly insert the pharyngeal sterile rayon swab (option) into the pharynx through the oral cavity, and collect the mucosal cuticle by swabbing the posterior wall of the pharynx and the palatine tonsils several times, centering around the reddening portion. Avoid touching saliva.

* The attached swabs are suitable for nasal sampling. Use a pharyngeal sterile rayon swab (option) for pharynx sampling.
2. Sample preparation

Tear the top seal of the extraction vial with the attached opener. Dip the swab into the specimen extract in the extraction vial immediately after the specimen collection and stir. Pinch the head of the swab from outside of the extraction vial and draw out the swab while squeezing. Use the squeezed solution as the test sample.

3. Precautions concerning sample preparation

1) If the sample is highly viscous as to clog the filter, dilute the sample with the saline two fold before use.
2) Use a nasal aspirate as it is for other test methods (example: isolation culture method etc).
3) If a part of the specimen is used for other test methods such as culture, place 1mL transport medium or saline in the tube in advance. Immediately after sampling specimen, insert the swab into the transport medium or saline in the tube and stir well. Use the portion of this solution for other test methods and dilute the remaining solution with the specimen extract two fold as the test sample for this kit.

4. Test procedure

1) Firmly attach the filter nozzle to the top of the extraction vial.
2) Hold the middle of the extraction vial with fingers and drip three drops of the sample (80～120 μL) into the sample placing area of the test plate. Hold the extraction vial perpendicularly and take care not to let the tip of the filter nozzle touch the sample placing area.
3) Observe the reading area of the test plate after 3～8 minutes and interpret the result.

Reading of the Results

Allow the samples to react according to the test procedure and read the black lines that appear in the reading area. (The reading area must be viewed from directly above.)

A-positive: When lines are seen at both [A] and [C] in the reading area (two lines), the result is read as positive for Influenza A viral antigen.

Note: When a very faint black line is seen in the reading area [A], the result is interpreted as positive.

B-positive: When lines are seen at both [B] and [C] in the reading area (two lines), the result is read as positive for Influenza B viral antigen.

Note: When a very faint black line is seen in the reading area [B], the result is interpreted as positive.

Negative: When no line is seen at [A] and [B] in the reading area but a line is seen only at [C] in the reading area (one line), the result is read as negative.

Note: When the line at [C] in the reading area is faint but visual, chromatographic development has occurred normally.

Retesting: When no line is seen at [C] in the reading area, there may be some problem with the test procedure or the reagent quality. The test should be performed again, using another test plate. If the amount of antigens is very high, a very thick line may be seen at [A] or [B] in the reading area and no line may be seen at [C] in the reading area. In that case, dilute the sample with the specimen extract by eleven fold and perform the test again.

Note: If the line is between each section of the reading area, the test is considered valid. (The boundary between the sections of the reading area is shown by the nicks on the reading window frame.)

Precautions when interpreting test results

1. Black lines seen both in the reading area [A] or [B] and [C] 3～8 minutes after sample dripping are interpreted as A-positive or B-positive. No black line in the reading area [A] and [B] even 8 minutes after sample dripping indicates a negative result.
2. An A-positive result does not rule out the presence of B-infection. Contrarily, a B-positive result does not rule out the presence of A-infection. In rare occasions, the result shows positivity to both A and B.

3. Do not use the test plate for a reading result beyond the judgment time as the result may change due to drying, etc.

4. A black line may not appear in the reading area [C] due to problems with the test procedure or the reagent quality. In such a case, the test should be performed again, using another test plate. If the same result is obtained in the re-test, try the test again using the sample diluted two fold with the saline as the black line may not appear in the reading area [C] due to a factor in the specimen or the effect of saliva.

5. In case of a very high antigen titer, a very dense line may be seen in the reading area [A] or [B] and no black line in the reading area [C]. In such a case, dilute the sample with the specimen extract and repeat the test. Example Method for dilution of sample: Apply 3 drops of a sample in a new extraction vial, mix thoroughly and use the solution as the test sample.

6. When discoloration is delayed due to some factor in the specimen or white discoloration is observed on the line in the reading area [A] or [B], the phenomenon may be improved by extending the judgment time for about a further 5 minutes after an 8 minutes standing.

**Performance**

1. **Performance**

   When sensitivity, specificity and reproducibility are tested according to Usage, Dosage described above, using (i) a positive control (3.0–3.9 × 10⁵ TCID₅₀/test in case of Influenza A viral antigen and 1.5–1.9 × 10⁶ TCID₅₀/test for Influenza B viral antigen), (ii) a weak positive control (3.0–3.9 × 10⁴ TCID₅₀/test for Influenza A viral antigen and 1.5–1.9 × 10⁵ TCID₅₀/test for Influenza B viral antigen) and (iii) a negative control (sample extract), the results conform to the following requirements.

   *¹ TCID₅₀/test: A 10⁻⁶ dilution series of samples is prepared and a 10⁻⁶ dilution at which 50% of MDCK (Madin Darby Canine Kidney) cells has a cytopathic effect (CPE), is expressed 10⁻₆ TCID₅₀/test, which is the viral infectivity titer.

   1) **Sensitivity test**

   When a positive control and a weak positive control are tested as samples, the result turns out positive.

   2) **Specificity test**

   When a positive control, a weak positive control and a negative control are tested as samples, the results are positive for the positive control and weak positive control, and the negative for a negative control.

   3) **Reproducibility test**

   When a positive control, a weak positive control and a negative control are tested in triplicate, the results are all positive for the positive control and weak positive control, and all negative for the negative control.

2. **Minimum detection limit**

   The minimum detection limit is 7.5 × 10³ TCID₅₀/test for Influenza A viral antigen and is 7.5 × 10⁴ TCID₅₀/test for Influenza B viral antigen.

3. **The result of the cross-reactivity test**

   No cross-reactivity was found in all the viruses and bacteria listed below.

   1) **Viruses except for Influenza A, B viruses**

      Adenovirus Type 1-6, 11, Influenza virus C, Parainfluenza virus Type 1-4, Respiratory syncytial virus (A)(B), Rhinovirus Type 2, Coxsackie virus Type A9,A16, B1-6, Echovirus Type 4, 6, 9,11, 14, 16,Cytomegalovirus , Human Metapneumovirus

   2) **Bacteria**

      Acinetobacter baumannii, Bacillus cereus, Bacteroides fragilis, Bordetella pertussis, Branhamella catarrhalis, Capnocytophaga ochracea, Citrobacter freundii, Eikenella corrodens, Enterococcus faecalis, Enterobacter cloacae, Fusobacterium nucleatum, Gardnerella vaginalis, Haemophilus influenzae, Haemophilus parainfluenzae, Kingella kingae, Klebsiella oxytoca, Lactobacillus casei, Mycobacterium abscessus, Mycobacterium avium, Mycobacterium intracellulare, Mycobacterium tuberculosis, Neisseria meningitides, Nocardia asteroides, Pasteurella multocida, Peptostreptococcus anaerobius, Porphyromonas asaccharolyticus, Prevotella intermedia, Prevotella melaninogenica, Salmonella choleraesuis(sub.minnesota), Serratia marcescens, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus bovis( II Group D),...
Streptococcus sp. group A,B,C,F,G, Streptococcus milleri, Streptococcus mutans, Streptococcus oralis, Streptococcus pneumoniae, Streptococcus sanguis,

3) Chlamydia

Chlamydia pneumoniae, Chlamydia psittaci

4. Reactivity with subtype Influenza viral strains.

Reactivity was found in the following strains:

1) Human origin type A virus
   A/Sendai/782/06(H1N1), A/Sendai/197/07(H1N1), A/Adachi/1/57(H2N2), A/Sendai/F492/06(H3N2), A/Sendai/958/07(H3N2), A/New Jersey/8/76(H1N1)

2) Human origin A/H1N1pdm
   A/Osaka/50/09(H1N1 pdm), A/Osaka/51/09(H1N1 pdm), A/Osaka/52/09(H1N1 pdm), A/Osaka/55/09(H1N1 pdm), A/Osaka/56/09(H1N1 pdm), A/Osaka/57/09(H1N1 pdm), A/Osaka/58/09(H1N1 pdm), A/Osaka/59/09(H1N1 pdm), A/Osaka/60/09(H1N1 pdm), A/Osaka/61/09(H1N1 pdm), A/Osaka/63/09(H1N1 pdm), A/Osaka/64/09(H1N1 pdm), A/Osaka/65/09(H1N1 pdm), A/Osaka/66/09(H1N1 pdm), A/Osaka/69/09(H1N1 pdm), A/Osaka/70/09(H1N1 pdm), A/Osaka/71/09(H1N1 pdm), A/Osaka/72/09(H1N1 pdm), A/Osaka/73/09(H1N1 pdm), A/Osaka/77/09(H1N1 pdm), A/Osaka/78/09(H1N1 pdm), A/Osaka/83/09(H1N1 pdm), A/Osaka/84/09(H1N1 pdm), A/Osaka/85/09(H1N1 pdm), A/Osaka/90/09(H1N1 pdm), A/Osaka/91/09(H1N1 pdm), A/Osaka/100/09(H1N1 pdm), A/Osaka/101/09(H1N1 pdm), A/Osaka/102/09(H1N1 pdm), A/Osaka/103/09(H1N1 pdm), A/Osaka/104/09(H1N1 pdm), A/Osaka/105/09(H1N1 pdm), A/Osaka/106/09(H1N1 pdm), A/Osaka/107/09(H1N1 pdm), A/Osaka/108/09(H1N1 pdm), A/Osaka/109/09(H1N1 pdm), A/Osaka/110/09(H1N1 pdm), A/Osaka/112/09(H1N1 pdm), A/Osaka/114/09(H1N1 pdm), A/Osaka/115/09(H1N1 pdm), A/Osaka/116/09(H1N1 pdm), A/Osaka/118/09(H1N1 pdm), A/Osaka/119/09(H1N1 pdm), A/Osaka/120/09(H1N1 pdm), A/Osaka/121/09(H1N1 pdm), A/Osaka/123/09(H1N1 pdm), A/Osaka/124/09(H1N1 pdm), A/Osaka/125/09(H1N1 pdm), A/Osaka/126/09(H1N1 pdm), A/Osaka/130/09(H1N1 pdm), A/Osaka/131/09(H1N1 pdm), A/Osaka/132/09(H1N1 pdm), A/Osaka/133/09(H1N1 pdm), A/Osaka/134/09(H1N1 pdm), A/Osaka/135/09(H1N1 pdm), A/Osaka/136/09(H1N1 pdm), A/Osaka/137/09(H1N1 pdm), A/Osaka/138/09(H1N1 pdm), A/Osaka/139/09(H1N1 pdm), A/Osaka/140/09(H1N1 pdm), A/Osaka/141/09(H1N1 pdm), A/Osaka/142/09(H1N1 pdm), A/Osaka/143/09(H1N1 pdm), A/Osaka/144/09(H1N1 pdm), A/Osaka/145/09(H1N1 pdm), A/Osaka/146/09(H1N1 pdm), A/Osaka/147/09(H1N1 pdm), A/Osaka/148/09(H1N1 pdm), A/Osaka/149/09(H1N1 pdm), A/Osaka/150/09(H1N1 pdm), A/Osaka/151/09(H1N1 pdm), A/Osaka/152/09(H1N1 pdm), A/Osaka/153/09(H1N1 pdm), A/Osaka/154/09(H1N1 pdm), A/Osaka/155/09(H1N1 pdm), A/Osaka/156/09(H1N1 pdm), A/Osaka/157/09(H1N1 pdm), A/Osaka/158/09(H1N1 pdm), A/Osaka/159/09(H1N1 pdm), A/Osaka/160/09(H1N1 pdm), A/Osaka/161/09(H1N1 pdm), A/Osaka/162/09(H1N1 pdm), A/Osaka/163/09(H1N1 pdm), A/Osaka/164/09(H1N1 pdm), A/Osaka/165/09(H1N1 pdm), A/Osaka/166/09(H1N1 pdm), A/Osaka/167/09(H1N1 pdm), A/Osaka/168/09(H1N1 pdm), A/Osaka/169/09(H1N1 pdm), A/Osaka/170/09(H1N1 pdm), A/Osaka/171/09(H1N1 pdm), A/Osaka/172/09(H1N1 pdm), A/Osaka/173/09(H1N1 pdm), A/Osaka/174/09(H1N1 pdm), A/Osaka/175/09(H1N1 pdm), A/Osaka/176/09(H1N1 pdm), A/Osaka/193/09(H1N1 pdm),

3) Type A virus of other than human origin
   A/duck/Tottori/723/80(H1N1), A/duck/Hokkaido/17/01(H2N3), A/duck/Mongolia/4/03(H3N8), A/duck/Czechoslovakia/1/56(H4N6), A/chicken/Yamaguchi/7/04(H5N1), A/whooper swan/Hokkaido/1/08(H5N1), A/whooper swan/Mongolia/3/05(H5N1), A/duck/Pennsylvania/10218/84(H5N2), A/duck/Hong Kong/820/80(H5N3), A/turkey/Massachusetts/3740/65(H6N2), A/shearwater/Australia/1/72(H6N5), A/chicken/Italy/99(H7N1), A/chicken/Pakistan/447/95(H7N3), A/seal/Massachusetts/1/80(H7N7), A/chicken/Netherlands/2586/03(H7N7), A/tufted duck/Shimane/124R/80(H7N7), A/turkey/Ontario/067(H8N4), A/turkey/Ontario/6118/68(H8N4), A/turkey/Wisconsin/66(H9N2), A/chicken/Germany/N/49(H10N7), A/duck/England/1/56(H11N6), A/duck/Alberta/60/76(H12N5), A/gull/Maryland/704/77(H13N6), A/mallard/Astrakhan/263/82(H14N5), A/duck/Australia/341/83(H15N8), A/black-headed gull/Sweden/5/99(H16N3), A/swine/Iowa/15/30(H1N1), A/swine/Niigata/1/77(H1N1), A/swine/Niigata/1/78(H1N1), A/swine/Toyama/1/78(H1N1), A/swine/Kanagawa/1/78(H1N1), A/swine/Shizuoka/1/78(H1N1), A/swine/Shimane/1/78(H1N1), A/swine/Hokkaido/80(H1N1), A/swine/Hokkaido/2/81(H1N1), A/swine/Saitama/96(H1N2), A/swine/Miyagi/5/03(H1N2), A/swine/Hong Kong/126/82(H3N2), A/swine/Obihiro/10/85(H3N2), A/swine/Chonburi/02(H3N2)

4) Human origin type B virus
   B/Sendai/1708/05, B/Sendai/942/07, B/Lee/40
5. Correlation with conventional test methods

1) The results of domestic clinical performance evaluation (in comparison with approved products)

1 Nasal swab

<table>
<thead>
<tr>
<th>Influenza A virus</th>
<th>Approved products</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Total</td>
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</tr>
</tbody>
</table>

Positive concordance rate: 100%
Negative concordance rate: 98.7%
Total concordance rate: 99.2%

*1 These three specimens are positive when tested by the viral isolation culture method.

<table>
<thead>
<tr>
<th>Influenza B virus</th>
<th>Approved products</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
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<td>287</td>
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<tr>
<td></td>
<td>Total</td>
<td>83</td>
<td>289</td>
<td>372</td>
</tr>
</tbody>
</table>

Positive concordance rate: 100%
Negative concordance rate: 99.3%
Total concordance rate: 99.5%

*2 One of these specimens is positive; one specimen is negative when tested by the viral isolation culture method. As for viral isolation culture method virus negative one specimen, RT-PCR method is positive.

2 Nasal aspirate

<table>
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<th>Influenza A virus</th>
<th>Approved products</th>
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<tbody>
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<td></td>
<td>Total</td>
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Positive concordance rate: 100%
Negative concordance rate: 99.1%
Total concordance rate: 99.3%

*3 These two specimens are positive when tested by the viral isolation culture method.

<table>
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<td></td>
<td>Total</td>
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</tbody>
</table>

Positive concordance rate: 100%
Negative concordance rate: 97.6%
Total concordance rate: 98.2%

*4 These five specimens are positive when tested by the viral isolation culture method.

3 Pharyngeal swab

<table>
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<th>Approved products</th>
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Positive concordance rate: 100%
Negative concordance rate: 95.4%
Total concordance rate: 96.6%

*5 These seven specimens are positive when tested by the viral isolation culture method.

<table>
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<th>Approved products</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
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</thead>
<tbody>
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<td>This product</td>
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<td>13</td>
<td>77</td>
</tr>
<tr>
<td></td>
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<td>131</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>64</td>
<td>144</td>
<td>208</td>
</tr>
</tbody>
</table>

Positive concordance rate: 100%
Negative concordance rate: 91.0%
Total concordance rate: 93.8%

*6 These thirteen specimens are positive when tested by the viral isolation culture method.
2) The results of domestic clinical performance evaluation (Comparison with isolation culture method)

1) Nasal swab

<table>
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<tr>
<th>Influenza A virus</th>
<th>Isolation culture method</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
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</tr>
<tr>
<td>Positive</td>
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<td>Negative</td>
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<td>196</td>
<td>302</td>
<td></td>
</tr>
</tbody>
</table>

*7 Eight of these specimens are positive; one specimen is negative when tested by the RT-PCR method.

<table>
<thead>
<tr>
<th>Influenza B virus</th>
<th>Isolation culture method</th>
<th>Positive</th>
<th>Negative</th>
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</thead>
<tbody>
<tr>
<td>This product</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>69</td>
<td>3</td>
<td>72</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>230</td>
<td>230</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>69</td>
<td>233</td>
<td>302</td>
<td></td>
</tr>
</tbody>
</table>

*8 One of these specimens is positive; two specimens are negative when tested by the RT-PCR method.

2) Nasal aspirate

<table>
<thead>
<tr>
<th>Influenza A virus</th>
<th>Isolation culture method</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>This product</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>58</td>
<td>3</td>
<td>61</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>3</td>
<td>188</td>
<td>191</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>61</td>
<td>191</td>
<td>252</td>
<td></td>
</tr>
</tbody>
</table>

*9 These three specimens are positive when tested by the RT-PCR method.

<table>
<thead>
<tr>
<th>Influenza B virus</th>
<th>Isolation culture method</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>This product</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>61</td>
<td>0</td>
<td>61</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>191</td>
<td>191</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>61</td>
<td>191</td>
<td>252</td>
<td></td>
</tr>
</tbody>
</table>

3) Pharyngeal swab

<table>
<thead>
<tr>
<th>Influenza A virus</th>
<th>Isolation culture method</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>This product</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>55</td>
<td>7*10</td>
<td>62</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>8</td>
<td>128</td>
<td>136</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>63</td>
<td>135</td>
<td>198</td>
<td></td>
</tr>
</tbody>
</table>

*10 Five of these specimens are positive; two specimens are negative by the RT-PCR method.

<table>
<thead>
<tr>
<th>Influenza B virus</th>
<th>Isolation culture method</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>This product</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>75</td>
<td>1*11</td>
<td>76</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>7</td>
<td>115</td>
<td>122</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>82</td>
<td>116</td>
<td>198</td>
<td></td>
</tr>
</tbody>
</table>

*11 This one specimen is negative when tested by the RT-PCR method.

Precautions when using and handling

I. Precautions when handling (including hazard control)

1) When the specimen extract gets into your eyes, immediately flush with a large quantity of water for 15 minutes or more. If you still feel strange, see a doctor for treatment.
2) When the specimen extract comes in contact with your hands or clothes, wash hands and clothes with soap or a large quantity of water.
2. Precautions when using

1) This product reacts only with Influenza A and B viruses and does not react with C virus.

2) This product is a reagent intended to rapidly detect Influenza A and B viral antigens. **A definite diagnosis should be made by an attending physician, in combination with clinical symptoms, the result of viral isolation culture and other test results.**

3) This product should be used in accordance with the procedure stated in the package insert.

4) In order to prevent deterioration, the products should be stored between 2−30°C, avoiding high temperatures, high humidity and direct sunlight.

5) **The aluminum pouches containing test plates should not be opened until they are about to be used.**

6) The sample placing area or the reading area of the test plate should not be touched with the hands.

7) A precipitate may be seen in the specimen extract but the product can be used as it is since the precipitate is confirmed not to affect test results.

8) Do not use any reagents beyond the expiry date.

9) The attached swabs are suitable for nasal sampling. Use a pharyngeal sterile rayon swab (option) for pharynx sampling.

10) Do not use the swab when it is broken, bent or stained.

11) Avoid the following usages because it may raise a possibility that the stick breaks.
   - the usage with excess force, strong pushing or excess twist load the stick, especially to the thin area of stick.
   - the usage with an intentional transformation (it bends, curves and fold back) to the stick.

12) Do not keep forcibly insertion operating when the insertion distance is obviously shorter than usually in the site. Especially, there is a possibility that the resistance imposes to the stick when the sample is collected from the infant and the patient with narrow nasal cavity. Do not rub strongly putting power on the stick in such case. Moreover, do not rotate the stick forcibly.

13) Any mucus mass on the tip of the swab should be gently removed with gauze. Do not wipe the tip too hard. Mucosal epidermal cells should remain on the tip for testing.

3. Precautions for disposal

1) Since test plates, swabs, extraction vials, filter nozzles, remaining samples, etc. may cause infections, they should be autoclaved (121°C, 20 min) or soaked in 0.1% Sodium hypochlorite for more than one hour. When reagents, remaining reagents or their accessories are disposed of, they should be treated in accordance with the laws and regulations concerning medical waste disposal and water pollution control.

2) In the specimen extract, 0.09% of sodium azide is contained as a preservative. When solutions containing sodium azide continue to be discarded over a long period of time, explosive metallic azide may be produced if a drain is made of metal. Therefore, they should be discarded with a large quantity of water.

**Storage, Validity**

Storage: store at 2−30°C

Expiry: 18 months

**Marketing Approval Holder in Japan**

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